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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/932,521

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Hans Herweijer

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03/25/2005

MIRUS CORPORATION  
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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/932,521

Applicant(s)

HERWEIJER ET AL.

Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

This application claims benefit to provisional application 60/225,946 filed August 17, 2000.

Applicants' amendment filed January 15, 2005, has been received and entered. Claims 16 and 18-20 have been canceled. Claims 1 has been amended. Claims 1-15 and 17 are pending and currently under examination.

### ***Inventorship***

As it appears that a party required by 37 CFR 1.48(a)(2) to submit a statement of facts may not be willing to submit such statement, applicant should consider either: a) submission of a petition under 37 CFR 1.183 to waive that requirement if the original named inventor(s) has assigned the entire right and interest to an assignee who has given its consent to the requested inventorship correction, MPEP § 201.03, Statement of Lack of Deceptive Intention, or b) refiling the application (where addition is needed under 37 CFR 1.53(b) with a new oath or declaration and any necessary petition under 37 CFR 1.47, or where only deletion is needed, either under 37 CFR 1.53(b) utilizing a copy of a prior oath or declaration under 37 CFR 1.63(d)(1)(iv), or under 37 CFR 1.53(d))(design applications only), thereby eliminating the need for a 37 CFR 1.48 request.

The statement of facts filed under 37 CFR 1.48(a) by an inventor or inventors to be added or deleted does explicitly state that the inventorship error occurred without deceptive intent on his or her part or cannot be construed to so state.

The inventorship has been amended.

### ***Claim Rejections - 35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 and 17 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed is withdrawn.

The amendments to the claims to delete prolonged has addressed the basis of the rejection.

Newly amended claims 1-15 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, the claims have been amended to recite the limitation "of longer than seven days". Applicants point to page 15, lines 14-16 for the literal support however while this provides literal support for the language, it is considered new matter because it does not appear that this is a unique and specific embodiment contemplated as the invention. Initially, it is noted that the phrase "of longer than seven days" is taken as a part from the definition of what is meant by an "extended period of time". Importantly, a complete review of the present specification indicates that there is no specific link between "of longer than seven days" and the teachings in the rest of the disclosure. On page 15, lines 14-16, at most one can construe that the a period of seven days would be the difference between a supercoiled plasmid and a linear

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nucleic derived therefrom, and importantly, not an absolute time of expression as recited in the claims but a difference in time in a specific comparison. Moreover, the recitation is taken out of context in that it is only a portion of an embodiment used to describe another term and fails to set forth limitations of amount of expression. This does not provide the basis for any non-viral, linear DNA because such DNA does not require to have been a supercoiled plasmid or being capable of becoming a supercoiled plasmid. At most this passage provides a comparison of plasmid DNA and linearized plasmid, and fails to provide support for the generic concept of any linear DNA. The specification as a whole teaches the delivery of linear DNA, in particular non-viral vectors, however fails to teach how these in general relates to prolonged expression or how this is assessed.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 1-15 and 17 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described. In this case, non-linear DNA can be generated through a variety of means which do not require the use of supercoiled plasmid DNA. The specification provides no guidance to the important elements required. The claims encompass providing any linear DNA and given simply that, the expression would inherently be expressed for seven days because there is no specific embodiments in the claims nor guidance in the instant specification to what elements are important or required to obtain the claimed expression. In addition, the claims

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indicate that expression is in a hepatocyte, however there is not structural requirement of the promoter set forth in the claim that even requires it to be active in the liver.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendments to the claims has obviated the basis of each of the specific rejections of record set forth in the previous office action.

***Claim Rejections - 35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims rejected under 35 U.S.C. 102(e) as being anticipated by Rolland *et al.* (US Patent 6,514,947) is withdrawn.

The cancellation of the claims have rendered the rejection moot.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Buttrick *et al.*, Circ Res. 1992 Jan;70(1):193-8, "Behavior of genes directly injected into the rat heart in vivo", teach that plasmid DNA can be directly injected in vivo and expressed in cardiac tissue.

Liang *et al.*, J Clin Invest. 1993 Mar;91(3):1241-6, "Targeted transfection and expression of hepatitis B viral DNA in human hepatoma cells" teach HepB viral antigens expressed from plasmids injected directly into the liver.

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Neither reference specifically teaches that plasmid preparations were linearized, however it is noted that most plasmid preparations result in a variety of forms of DNA, including supercoiled, nicked and linear plasmids.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.



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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach

*Joe Voitach*  
AUG 32